CAUSE NO. _____

STATE OF TEXAS, Plaintiff	§	IN THE DISTRICT COURT OF
VS.	§	
COLON THERAPEUTICS, INC., and JIMMY JOHN GIROUARD, individually, Defendants.	§	DALLAS COUNTY, T E X A S
	§	____ JUDICIAL DISTRICT

PLAINTIFF'S ORIGINAL PETITION

TO THE HONORABLE JUDGE OF SAID COURT:

COMES NOW, the STATE OF TEXAS, plaintiff, acting by and through Attorney General GREG ABBOTT, filing Plaintiff's Original Petition complaining of and against Defendants COLON THERAPEUTICS, INC., and JIMMY JOHN GIROUARD, individually, ("Defendants"), based on their manufacturing, advertising, and selling of colon irrigation systems in violation of state law and would respectfully show the court the following:

JURISDICTION

1. This suit is brought by Attorney General GREG ABBOTT through his Consumer Protection Division in the name of the STATE OF TEXAS and in the public interest under the authority granted to him by §431.047 (b) of the Texas Food, Drug and Cosmetic Act, TEX. HEALTH AND SAFETY CODE ANN. ("TFDCA") and any regulations promulgated pursuant to this law, upon the grounds that the Commissioner of Health of the State of Texas and his authorized agents find that Defendants have violated and have threatened to violate provisions of §431.021 of the TFDCA.

2. This suit is also brought by Attorney General GREG ABBOTT through his Consumer Protection Division in the name of the State of Texas under the authority granted to

him by §17.47 of the Texas Deceptive Trade Practices Act, TEX. BUS. & COM. CODE ANN. §17.41 *et seq.*, ("DTPA") upon the grounds that Defendants have engaged in false, misleading and deceptive acts and practices in the conduct of trade or commerce as defined and declared unlawful by §17.46 (a) and (b) of the DTPA.

PARTY DEFENDANTS

3. Defendant JIMMY JOHN GIROUARD is an individual who owns and directs Defendant COLON THERAPEUTICS, INC., at 2909 Main Avenue, Groves, Texas 77619 in Jefferson County. Defendant JIMMY JOHN GIROUARD may be served with process by serving him at his home business address.

4. Defendant COLON THERAPEUTICS, INC., may be served with process through serving its registered agent, Defendant JIMMY JOHN GIROUARD, its President and owner at 2909 Main Avenue, Groves, Texas 77619.

VENUE

5. Venue of this action lies in Dallas County on the basis of §17.47(b) of the DTPA and §431.047 (c) and §431.0585(d) of the TFDCA by virtue of the fact that Defendants engaged in the business of advertising, promoting and selling Defendants' prescription colon irrigation systems, including rectal nozzles[1], in Dallas County, Texas, particularly to Eternal Health, Inc., and Cynthia Pitre and to Jennifer Jackson d/b/a Body Cleanse Spa. In addition, Defendants advertised and promoted their training services on how to perform colon hydrotherapy in Dallas County.

[1]In this petition, the phrase "prescription colon irrigation system" includes all parts of the system required to provide colon cleansing, including rectal nozzles, as the nozzles are accessories of the system and cannot be used separately from the system.

PUBLIC INTEREST

6. By reason of the institution and operation of the unlawful practices set forth herein, Defendants have and will cause immediate and irreparable injury, loss and damage to the State of Texas, and its citizens, and will also cause adverse effects to legitimate business enterprise which conducts its trade and commerce in a lawful manner in this State. Therefore, the Attorney General of the State of Texas believes and is of the opinion that these proceedings are in the public interest.

TRADE AND COMMERCE

7. Defendants are engaged in trade and commerce, as that term is defined by §17.45(6) of the DTPA, in that they were engaged in the business of advertising, marketing, manufacturing, and selling prescription colon irrigation systems, including rectal nozzles and training services in Texas.

NOTICE BEFORE SUIT

8. Pursuant to §17.47(a) of the Deceptive Trade Practices Act, contact has been made with the Defendants herein to inform them of the unlawful conduct alleged herein, by letter mailed by certified mail, return receipt requested.

ACTS OF AGENTS

9. Whenever in this petition it is alleged that Defendants did any act or thing, it is meant that Defendants performed or participated in such act or thing or that such act was performed by the officers, agents or employees of said Defendants, and in each instance, the officers, agents or employees of said Defendants that were then authorized to and did in fact act on behalf of Defendants or otherwise acted under the guidance and direction of the Defendants.

OVERVIEW OF DEFENDANTS' OPERATION

10. Defendants manufacture prescription colon irrigation systems, at 2909 Main Avenue, Groves, Texas 77619. Defendants identify their colon irrigation system as "Jimmy John III" and their rectal nozzles for use with this system as "Jimmy John III rectal nozzles".

11. FDA informed Defendants that the Jimmy John III rectal nozzles were cleared for marketing as prescription medical devices in response to Defendants' submissions K973256 and K972455. (See attached Exhibit A and B, FDA Clearance Letters.) Therefore, Defendants' rectal nozzles are required to bear the statement on their labels that "Federal Law restricts this device to sale by or on the order of a _____", the blank to be filled in with the word 'physician, dentist, veterinarian, or with the description designation of any other practitioner licensed by the law of the State in which he practices to use and order the use of the device.[2]

12. All premarket clearance letters that FDA sent to Defendants cleared the Jimmy John III colon irrigation system and rectal nozzle only for the same intended use, as defined in 21 CFR 876.5210, for "colon cleansing when medically indicated under the supervision of a practitioner, such as before radiological or endoscopic examinations and as Class II.

FDA Warning Letter Affirming Prescription Medical Device Status of Defendants' Devices

13. On October 23, 2003, FDA sent a Warning Letter to Defendants informing them that their "...colonic irrigation products are a system consisting of a rectal nozzle, a water tank, flow controller, temperature indicator and alarm, ultraviolet lamp, water filter, and a series of valves and pipes. This configuration is consistent with the type of device defined in Title 21,

[2]Under Texas law, the only practitioner licensed to use prescription colon irrigation systems on humans are those licensed by the Texas Board of Medical Examiners. Therefore, in this petition, when the term "practitioner" is used, it refers only to those persons licensed by the Texas Board of Medical Examiners.

Code of Federal Regulations (CFR), Section 876.5220 (colonic irrigation system)." (See Exhibit C, FDA Warning Letter.)

14. In this Warning Letter, FDA informed Defendants that "(w)hen FDA cleared the 510(k)s for the Jimmy John rectal nozzles, an accessory of the Jimmy John colonic irrigation system, we indicated that our clearance was limited to prescription use only." FDA continues that both the colon irrigation system and the rectal nozzles were cleared for the same intended use as defined in 21 CFR 876.5220 and concludes that the Jimmy John III colon irrigation system is misbranded because its labeling fails to bear the prescription legend.

15. FDA warned Defendants that their clearance of "...Jimmy John III Colonic Irrigation Systems covers for colon cleansing when medically indicated under the supervision of a practitioner." FDA further advises Defendants that any therapeutic claims that they make for these products that exceeded the cleared intended use would make the products Class III devices and require approval prior to marketing.

16. FDA also determined that Defendants possessed information that reasonably suggested that their Jimmy John III colon irrigation system may have caused or contributed to the perforation of the bowel of a 72 year old patient who died because the use of Defendants' colonic irrigation system and rectal nozzle may have been a factor in this adverse incident. FDA notified Defendants that they were required to file a report with FDA of this adverse event within 30 days of becoming aware of the incident and that Defendants' failure to file a medical device report ("MDR") causes the Jimmy John colonic devices to be misbranded under section 502(t) of the Federal Act.

17. FDA also notified Defendants that their medical device reporting procedures are still deficient because they do not include "death" as one of the MDR reportable events and the

procedures do not call for the firm to evaluate the cause of the problem as required by 21 CFR 803.50(b)(2).

Defendants Ignore FDA Restrictive Clearance of Prescription Colon Irrigation Devices

18. Despite such restrictive clearance for Defendants' colon irrigation systems by FDA, Defendants advertise and distribute in commerce thousands of prescription colon irrigation systems throughout Texas, much of the United States, and foreign countries. Defendants advertised, offered to sale, and sold their prescription colon irrigation systems without an order or authorization to purchase or possess these devices from a practitioner, as required by state and federal law, and, therefore, misbranded them.

19. Defendants specifically delivered prescription colon irrigation devices to consumers in Dallas County, Texas to Eternal Health, Inc., and Cynthia Pitre and to Jennifer Jackson d/b/a Body Cleanse Spa without an order or authorization to purchase or possess these devices from a practitioner.

20. Defendants advertised and marketed their prescription colon irrigation systems for other purposes than the approved intended use of colon cleansing when medically indicated as shown below. Defendants' advertising and marketing of these prescription devices for other uses, including for general well being, that have not been approved by the FDA adulterated these devices.

21. Defendants continued to sell prescription colon irrigation systems without practitioner involvement even after they had been informed by the Texas Department of Health ("TDH"), on December 12-13, 2002 that the colon irrigation systems that Defendants manufactured, offered for sale, sold, and advertised were prescription medical devices and could only be purchased and/or possessed, upon the order of a practitioner licensed in Texas to

purchase and/or authorize the possession of prescription colon irrigation systems for use on humans.

22. In their owner manual, Defendants represent that colon cleansing using Jimmy John III prescription colon irrigation systems can "...be administered in preparation for a lower endoscopic examination...surgery and child birth. The procedure has provided assistance with some conditions such as constipation, diarrhea, acute fecal impaction, atonic colon, flatulence or bloating, mild hemorrhoids, intestinal toxemia, nutrient supplementation, bowel stimulation and bowel training in para/quadriplegics....Colonics may also be administered to detoxify the colon, as well, maintenance of lower bowel hygiene."

23. Defendants advertise on the internet site found at www.colontherapeuticsinc.com their colon irrigation systems will assist the colon's natural ability to absorb nutrients back into the body, minimize the autointoxication of toxic materials in the colon, reduce the stagnation in the colon and minimize the exposure of the colon walls to potential cancer causing agents, and for general well-being; Defendants misbranded their prescription colon irrigation systems under state and federal law by advertising them for uses other than the FDA approved uses.

24. .Defendants failed to disclose on the internet site, in their owner's manual, or in their training of colon hydrotherapists that prescription colon irrigation systems may be possessed or purchased to use on humans only by order of a practitioner and that their use must be by or under the supervision of a practitioner with an order or prescription for each procedure.

25. Defendants failed to disclose on the internet site, in their owner's manual, or in their training that their colonic irrigation system has been approved by the FDA only for colon cleansing, when medically indicated, such as before radiologic or endoscopic examinations and not for the uses for which Defendants advertise the procedures. Defendants's false advertising

misbranded their colon irrigation systems by advertising the use of these devices for unapproved uses.

Inspections of December 12-13, 2002:

26. On December 12-13, 2002, an investigator from the Texas Department of Health ("TDH") inspected Defendants' office at 2909 Main Avenue, Groves, Texas 77619, as a result of a complaint that a 72 year old woman died on August 14, 2002, after using a Jimmy John III colon irrigation system, at Eternal Health, Inc., and Cynthia Pitre's Irving office on April 21, 2002.

27. TDH cited Defendants for the following objectionable conditions or practices:

a. Defendants distributed prescription devices, including the Jimmy John III colon irrigation system and rectal nozzles, to persons other than a licensed practitioner and without an order or prescription of licensed practitioner for use in the course of the practitioner's professional practice;

b. Defendants failed to file a report with FDA pursuant to the Medical Device Reporting regulation within 30 days of becoming aware of information that reasonably suggested that their marketed devices may have caused or contributed to a death or serious injury;

c. Defendants had not developed written Medical Device Reporting procedures to include documentation, record keeping requirements, and a standardized review process;

d. Defendants' labels and labeling for the Jimmy John III colon irrigation device (not the nozzles) do not make reference to the device being a prescription device and do not contain the statement "Caution: Federal law restricts this device to sale by or on the order of a physician;

e. Defendants' internet website at www.colontherapeuticsinc.homestead.com contains statements regarding colon cleansing for general well being as "Almost anyone can find benefit from internal cleansing of some kind." and "...when a periodic cleansing of the colon could help reduce the stagnation in the colon and minimize the exposure of the colon walls to potential cancer causing agents";

f. Defendants have presented no evidence to suggest that the Jimmy John III colon irrigation system manufactured and distributed by your firm for investigational study purpose (general well being) is the subject of an investigational deice exemption approved by FDA; and

g. Defendants' records of all changes to documents were not maintained, specifically, the Owner's Manual for the Jimmy John III has been revised approximately three times with no document control for any of the revisions.

28. During the inspection of Eternal Health, Inc., and Cynthia Pitre's facility in November, 2002, Defendant JIMMY JOHN GIROUARD and Dick Hoenninger, Executive Director of the International Association for Colon Hydrotherapy mislead Cynthia Pitre, on a telephone call, that her involvement in a study to reclassify colon irrigation systems for general well being qualified her to possess and use the prescription colon irrigation systems as part of an Investigational Device Exemption without a practitioner's order or authorization.

29. Neither Defendant JIMMY JOHN GIROUARD nor Dick Hoenninger could provide documentation that an IDE study involving these devices was approved by FDA, and in fact, FDA has subsequently issued a warning letter to Hoenninger and IACT that their investigational study was not approved by FDA and violates federal law.

30. When inspecting Eternal Health, Inc., and Cynthia Pitre's facility in November, 2002, TDH determined that Eternal Health, Inc., and Pitre had purchased and received in

commerce in Dallas County, Texas, seven of Defendants' colon irrigation systems and thousands of Jimmy John III rectal nozzles from Defendants without any practitioner authorization.

31. On December 12-13, 2002, during TDH's inspection of Defendants' office, TDH found that none of Defendants' files contained any order or authorization from a practitioner allowing the purchaser to possess or purchase prescription colon irrigation systems from Defendants.

Inspection of July 7, 2003:

32. On July 7, 2003, TDH inspected Defendants to follow-up to determine if they had records of orders or authorization for each sale from a practitioner. TDH determined that orders or authorization from a practitioner were still not being required from at least four purchasers and that Defendants had sold at least 650 prescription colon irrigation rectal nozzles, without orders or authorization from a practitioner.

OVERVIEW OF REGULATION OF PRESCRIPTION MEDICAL DEVICES

33. The Texas Food, Drug, and Cosmetic Act ("TFDCA") lists acts and the causing of acts that are unlawful and prohibited, including, but not limited to, manufacturing or introducing into commerce misbranded or adulterated medical devices; misbranding or adulterating medical devices in commerce; and the dissemination of any false advertisement. TDH determines if the offering for sale, sale, or use of a medical device violates any prohibited acts depending on the classification and regulation of each medical device by the Federal Food and Drug Administration ("FDA").

FDA Regulates and Classifies Medical Devices According to Intended Use

34. FDA regulates and classifies medical devices for use in humans according to their intended use, relying upon the manufacturer or distributor's labeling of the device to determine its intended use. FDA is responsible for classifying and approving medical devices after they

determine whether they are safe and effective for their stated intended uses.

35. FDA has classified colon irrigation systems intended for "colon cleansing, when medically indicated, such as before radiologic or endoscopic examinations" as Class II medical devices when used for this purpose in 21 C.F.R. §876.5220 (b)(1). Colon irrigation systems, including rectal nozzles are described as usually consisting of a container for fluid; the tubing; the nozzle; a system which enables the pressure, temperature, or flow of water through the nozzle to be controlled; a console-type toilet and necessary fittings to allow the device to be connected to water and sewer pipes; and electrical power to heat the water.

36. FDA approved the Jimmy John III colon irrigation system and the Jimmy John rectal nozzle, manufactured by Defendants, as "substantially equivalent" to other pre-existing colon irrigation systems used for colon cleansing, when medically indicated, such as before radiologic or endoscopic examinations based on premarket notification submissions to the FDA pursuant to § 510(k) of the FFDCA, 21 U.S.C. § 360(k). Therefore, these devices are Class II medical devices by regulation for this purpose and can only be used for the approved intended use.

37. FDA has also classified colon irrigation systems for other uses than the intended use authorized in 21 C.F.R. §876.5220 (b)(1). However, when the intended use is for "other uses, including colon cleansing routinely for general well being" as listed in 21 C.F.R. §876.5220 (b)(2), then these colon irrigation systems are classified as class III medical devices .

38. Designation as Class III medical devices requires that any colonic irrigation system to be used for purposes, other than those approved in 21 C.F.R. §876.5220 (b)(1), shall have an approved premarket approval ("PMA") in effect before being placed in commercial distribution to show that the device is safe and effective for the new intended use pursuant to 21 C.F.R. §876.5220 (c).

39. FDA requires that, unless specifically exempted, any medical device must have "adequate directions for use" as defined in 21 C.F.R. § 801.5 to mean directions under which the layperson can use a device safely and for the purposes for which it is intended. Unless subject to an exemption, a medical device must have "adequate directions for use" or it cannot be sold to or used by a lay person.

FDA Considers All Colon Irrigation Systems To Be Prescription Medical Devices

40. FDA defines a prescription device in 21 C.F.R. § 801.109 to be a device which, because of any potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use is not safe except under the supervision of a practitioner licensed by law to direct the use of such device, and hence for which "adequate directions for use" cannot be prepared.

41. Under FDA regulations (21 C.F.R. § 801.109), a medical device is exempt from having "adequate directions for use" only if it is in the possession of a practitioner licensed by state law to use or order the use of such device; sold only to or on the prescription or other order of such practitioner for use in professional practice; and the label has to bear the statement "Caution: Federal law restricts this device to sale by or on the order of a _____, to be filled in with the descriptive designation of any practitioner licensed by state law in which he practices to use or order the use of the device.

42. The FDA considers the colon irrigation systems manufactured, offered for sale, sold, and advertised by Defendants to be prescription medical devices, as defined in 21 C.F.R. § 801.109. As such, FDA has determined that Defendants' devices cannot bear adequate directions for safe use by a layperson, and therefore must comply with the exemption requirements in paragraph 41. FDA's Warning Letter, dated October 23, 2003, to Defendants reaffirms this prescription medical device status of the Jimmy John III and the Jimmy John III rectal nozzles.

43. In addition, prescription medical devices are restricted devices because they are subject to certain controls related to sale, distribution, or use as specified in §520(e)(1) of the Federal Food, Drug and Cosmetic Act. Restricted devices are similarly defined in 25 T.A.C. §229.433 (27). Because Defendants' colon irrigation systems are prescription medical devices, under Texas law their devices are also restricted devices pursuant to 25 T.A.C. §229.433 (27) and 25 T.A.C. §229.433 (23).

Defendants' Prescription Colon Irrigation Systems Are Dangerous Drugs Under Texas Law

44. Prescription colon irrigation systems are "dangerous drugs" pursuant to §483.001 (2) of the Texas Dangerous Drug Act because these devices bear or are required to bear a legend to comply with federal law regarding their sale as prescription medical devices pursuant to 21 C.F.R. § 801.109.

45. Under Texas law, only those practitioners listed in § 483.001(12) of the Texas Dangerous Drugs Act, also defined in 25 T.A.C. §229.433 (22), are authorized to purchase, possess, use or order the use of prescription or restricted medical devices which includes prescription colon irrigation systems. The only practitioners licensed in Texas who can purchase, possess, use or order the use of colon irrigation systems on humans in the course of their professional practice are those practitioners licensed by the Texas Board of Medical Examiners.

DEFENDANTS' DEVICES ARE MISBRANDED

46. As set out in paragraphs 1 through 45 and incorporated herein, Section 431.112(f)(1) of the TFDCA provides that a device is misbranded unless its labeling bears adequate directions for use or unless the device has been exempted from those requirements by regulation. Since the prescription colon irrigation systems manufactured by Defendants cannot bear instructions for safe use by a layperson and are not exempt from this requirement, Defendants may legally only sell their devices to a licensed practitioner.

47. Defendants failed to restrict sale of their prescription colon irrigation systems to practitioners as defined by §483.001(12) of The Dangerous Drug Act.

48. Defendants' selling of prescription colon irrigation systems without evidence that the purchase was by or authorized by a practitioner misbrands these device pursuant to § 431.112 (f) of the TFDCA.

49. In addition, Defendants' prescription colon irrigation systems are also restricted devices, as defined in by 25 T.A.C. §229.433 (27), since they are subject to certain controls related to the sale, distribution, or use. Therefore, Defendants' sale of restricted devices without authorization by a practitioner also misbrands these device pursuant to § 431.112 (r) of the TFDCA.

50. Under the terms of § 431.021 (a) and (b) of the TFDCA, the introduction into commerce of misbranded devices or the misbranding of any device in commerce in Texas is unlawful and prohibited. Defendants' sale of prescription and restricted medical devices without authorization by a practitioner misbrands these devices in Texas.

51. Defendants' labels and labeling for their prescription colon irrigation systems, not the nozzle, do not make reference to the device being a prescription device and do not contain the statement "Caution: Federal law restricts this device to sale by or on the order of a _____" licensed by the state to use and order the use of such device, and, therefore, these devices are misbranded.

DEFENDANTS' DEVICES ARE ADULTERATED

52. As set out in paragraphs 1 through 51 and incorporated herein, Defendants' prescription colon irrigation systems are Class III medical devices when advertised, sold, or used for purposes other than those stated in 21 C.F.R. §876.5220 (b)(1), including colon cleansing

routinely for general well being; to detoxify the colon; to treat constipation; diarrhea. acute fecal impaction, atonic colon, flatulence or bloating, mild hemorrhoids, intestinal toxemia, nutrient supplementation; for bowel stimulation and bowel training in para/quadriplegics. Defendants' prescription colon irrigation system have not received premarket approval for such uses and are not exempted from such approval.

53. Defendants' prescription colon irrigation systems are Class III medical devices when used for other uses as listed above, but Defendants have introduced them into commerce even though they did not receive such approval. A device is adulterated if it is a Class III medical device, whether by statute or regulation, and is in the marketplace without receiving approval from FDA.

54. Defendants' prescription colon irrigation systems are adulterated under state law, according to §431.111(f)(1)(A) of the TFDCA. Section 431.111 states that a device shall be deemed to be adulterated :

> **(**f)(1) if it is a class III device:
>
> (A)(i) that is required by a regulation adopted under Section 515(b) of the federal Act to have an approval under that section of an application for premarket approval and that is not exempt from Section 515 as provided by Section 520(g) of the federal Act; and
>
> (ii)(I) for which an application for premarket approval or a notice of completion of a product development protocol was not filed with the United States Food and Drug Administration by the 90th day after the date of adoption of the regulation; or
> (II) for which that application was filed and approval was denied or withdrawn, for which that notice was filed and was declared incomplete, or for which approval of the device under the protocol was withdrawn.

55. Under the terms of § 431.021 (a)and (b) of the TFDCA, the introduction into commerce of an adulterated device and the adulteration of any device in commerce in Texas is unlawful and prohibited. Defendants violate § 431.021(a) and (b) of the TFDCA with each intended use that FDA codifies as a Class III use, including for general well being, since these

devices have not been received pre-market approval by FDA, as required, to show their safety and effectiveness for Class III uses.

DEFENDANTS' ADVERTISEMENTS ARE FALSE, MISLEADING OR DECEPTIVE

56. As set out in paragraphs 1 through 55 and incorporated herein by reference, Defendants represented that their prescription colon irrigation systems have uses other than those for which FDA has allowed the devices to be sold or used, including for general well being. Defendants' representations for the use of prescription colon irrigation systems, for unapproved uses constitute false advertisements in violation of § 431.021(f) of the TFDCA.

57. Defendants also have violated § 431.021(f) of the TFDCA because Defendants' representations of the illegal use of all their prescription colon irrigation systems in their internet site, advertisements, manuals, sales presentations, and training constitute false advertising under the TFDCA because they solicited persons to purchase prescription medical devices and training services which are unlawful and violate § 431.021(b) of the TFDCA.

58. Defendants advertise and promote prescription colon irrigation systems for self-medication or for use without practitioner supervision through their internet site, advertising, training, and manuals. Defendants do not disclose in their advertising and selling of these devices that these acts are unlawful and prohibited by the TFDCA.

59. Defendants' advertisements and representations that patients should insert the rectal nozzle themselves fail to disclose that such devices are cleared only to be used by a practitioner or under the supervision of a practitioner because these devices are not approved for self-use and constitute false advertising in violation of § 431.021(f) of the TFDCA .

60. Such representations listed above constitute advertising within the definition set out in §431.002(1) of the TFDCA since they are intended to induce consumers to purchase Defendants' prescription colon irrigation devices and training services for unapproved uses of

prescription colon irrigation systems and without involvement of a practitioner licensed in Texas to use or order the use of such devices.

61. Any such advertisement by Defendants of a prescription medical device directed toward the public that does not disclose that a practitioner licensed by the state to use such a device must order or authorize its possession or purchase; must order the use of or use the prescription colon irrigation systems; and advertisements for unapproved uses are declared to be false by §431.182(a) of the TFDCA.

PROHIBITED ACTS

62. Defendants, as set out in paragraphs 1 through 61 and incorporated herein by reference, have committed or caused to be committed the following acts prohibited and declared to be unlawful by §431.021 of the TFDCA:

a. Misbranding prescription colon irrigation systems by selling to someone other than a practitioner licensed by state law to purchase such devices, in violation of §431.021(a) and/or (b);

b. Misbranding prescription colon irrigation systems by causing someone other than a practitioner licensed by state law to use such devices, in violation of §431.021(a) and/or (b);

c. Falsely advertising or representing that prescription colon irrigation systems do not need to be purchased, possessed, used, or supervised by a practitioner licensed by state law to use such devices in violation of §431.021(f);

d. Misbranding prescription colon irrigation systems by advertising and representing that such devices can be used for uses not approved by FDA, in violation of §431.021(a) and/or (b);

e. Adulterating prescription colon irrigation systems by advertising such devices for uses not approved by FDA, in violation of §431.021(a) and/or (b);

f. Adulterating prescription colon irrigation systems by causing such devices to be used for uses not approved by FDA, in violation of §431.021(a) and/or (b);

g. Falsely advertising that prescription colon irrigation nozzles, as approved by the FDA, can be self-inserted when FDA has cleared these nozzles only for use by a practitioner or under the supervision of a practitioner, in violation of §431.021(f);

h. Falsely advertising that prescription colon irrigation systems are effective for general well-being when FDA has not approved these devices for such use in violation of §431.021(f);

i. Falsely advertising and representing an investigational study using prescription colon irrigation systems without an investigational device exemption approved by the FDA, in violation of §431.021(f);

j. Introducing or delivery or causing the introduction or delivery into commerce of a misbranded or adulterated prescription colon irrigation systems, in violation of §431.021(a);

k. Misbranding or causing the misbranding of a prescription colon irrigation system in commerce, in violation of §431.021(b);

l. Adulteration or causing the adulteration of a prescription colon irrigation system in commerce, in violation of §431.021(b);

m. Receiving or causing the receiving in commerce of a prescription colon irrigation system that is adulterated or misbranded, in violation of §431.021(c);

n. Disseminating false advertising or causing the dissemination of false advertising, in violation of §431.021(f);

o. Failing to provide a notice required by Section 510 (k) of the Federal Act prior to introducing into commerce a colon irrigation system, including rectal nozzles, for a new or unapproved use, unless exempt by a 520(g) investigational device exemption, in violation of § 431.021(t)(1)(A);

p. Failing to comply with any requirement required by 520(g) of the Federal Act by furnishing any notification or information regarding any investigational device exemption in which Defendant is involved, in violation of § 431.021(t) (1)(B);

q. Failing to comply with federal medical device reporting requirement to report a serious injury and/or death, as required by 21 CFR § 803 and Section 519 of the federal Act, in violation of § 431.021(t) (1)(B);

r. Falsely advertising that prescription colon irrigation systems as approved by the FDA can be self-administered when FDA has not approved these devices for such uses, in violation of §431.021(f); and

s. Manufacturing prescription colon irrigation systems in Texas and failing to disclose to each purchaser through labeling or a label that the device is a prescription device in violation of §431.021(a) and/or (b).

VIOLATIONS OF THE DTPA

63. Defendants, as set out in paragraphs 1 through 67 and incorporated herein by reference, in the course and conduct of trade and commerce, have directly and indirectly engaged in false, misleading, deceptive and unconscionable acts and practices declared unlawful by §17.46 (a) and (b) of the Texas Deceptive Trade Practices Act, including but not limited to:

a. Causing confusion as to the approval of a good by selling prescription colon irrigation systems without the authorization or order of a practitioner licensed in Texas;

b. Failing to disclose that prescription colon irrigation systems are only to be sold under the order or authorization of a practitioner licensed to use and order the use of such device;

c. Failing to disclose in any advertising, representations, training or publications that prescription colon irrigation systems are only to be used under the supervision of a practitioner licensed to use and order the use of such device;

d. Failing to disclose in any advertising, representations, training, or publications that colon cleansing using prescription colon irrigation systems can only be performed upon the order of a licensed practitioner in Texas;

e. Falsely representing to a consumer that colon cleansing using prescription colon irrigation systems can legally be performed without the supervision or order of a practitioner licensed to use or order the use of such device;

f. Falsely advertising that colon cleansing using prescription colon irrigation systems are appropriate for self-administration when they are not; and

g. Failing to disclose that Defendants' prescription colon irrigation systems are approved only for colon cleansing, when medically indicated, such as before radiologic or endoscopic examinations only.

64. Moreover, the Consumer Protection Division has reason to believe that the above actions specifically violate §17.46 (a) and the following provisions of §17.46 of the DTPA:

(b)(2) causing confusion or misunderstanding as to the source, sponsorship, approval, or certification of goods or services;

(b)(5) representing that goods or services have sponsorship, approval, characteristics, ingredients, uses, benefits or quantities which they do not have;

(b)(7) representing that goods or services are of a particular standard, quality, or grade, or that goods are of a particular style or model, if they are of another;

(b)(24) failing to disclose information concerning goods or services which was known at the time of the transaction when such failure to disclose such information was intended to induce the consumer into a transaction into which the consumer would not have entered had the information been disclosed.

INJURY TO CONSUMERS

65. By means of the foregoing unlawful acts and practices which were producing causes of injury to the persons affected, Defendants have acquired money or other property from identifiable persons to whom such money or property should be restored, or who in the alternative are entitled to an award of damages.

CONTINUING VIOLATIONS

66. By reason of the institution and continued operation of the acts and practices described in paragraphs 1 through 65 above, Defendants have violated and will continue to violate the laws as hereinabove alleged. Defendants, unless restrained by this Honorable Court, will continue violating the laws of the State of Texas and injury, loss and damage will result to the State of Texas and to the general public. Defendants have violated and continue to violate these sections of the TFDCA and the DTPA.

PRAYER

67. WHEREFORE, PREMISES CONSIDERED, Plaintiff prays that Defendants COLON THERAPEUTICS, INC., and JIMMY JOHN GIROUARD, individually, be cited according to law to appear and answer herein; that after due notice and hearing a TEMPORARY INJUNCTION be issued and upon final hearing a PERMANENT INJUNCTION be issued restraining and enjoining Defendants and by their agents, servants, employees, and representatives from making the representations, doing the acts, and engaging in the practices set out in the preceding paragraphs as well as from making the following representations and doing the

following acts and engaging in the following practices in the pursuit and conduct of trade or commerce within the State of Texas as follows:

a. Misbranding prescription colon irrigation systems by selling to someone other than a practitioner licensed by state law to purchase such devices;

b. Misbranding prescription colon irrigation systems by causing someone other than a practitioner licensed by state law to use such devices;

c. Falsely advertising or representing that prescription colon irrigation systems do not need to be purchased, possessed, used, or supervised by a practitioner licensed by state law to use such devices;

d. Misbranding prescription colon irrigation systems by advertising and representing that such devices can be used for uses not approved by FDA;

e. Adulterating prescription colon irrigation systems by advertising such devices for uses not approved by FDA;

f. Adulterating prescription colon irrigation systems by causing such devices to be used for uses not approved by FDA:

g. Falsely advertising that prescription colon irrigation nozzles, as approved by the FDA, can be self-inserted when FDA has cleared these nozzles only for use by a practitioner or under the supervision of a practitioner;

h. Falsely advertising that prescription colon irrigation systems are effective for general well-being when FDA has not approved these devices for such use;

i. Falsely advertising and representing an investigational study using prescription colon irrigation systems without an investigational device exemption approved by the FDA;

j. Introducing or delivery or causing the introduction or delivery into commerce of a misbranded or adulterated prescription colon irrigation systems;

k. Misbranding or causing the misbranding of a prescription colon irrigation system in commerce;

l. Adulteration or causing the adulteration of a prescription colon irrigation system in commerce;

m. Receiving or causing the receiving in commerce of a prescription colon irrigation system that is adulterated or misbranded;

n. Disseminating false advertising or causing the dissemination of false advertising;

o. Failing to provide a notice required by Section 510 (k) of the Federal Act prior to introducing into commerce a colon irrigation system, including rectal nozzles, for a new or unapproved use, unless exempt by a 520(g) investigational device exemption;

p. Failing to comply with any requirement required by 520(g) of the Federal Act by furnishing any notification or information regarding any investigational device exemption in which Defendant is involved;

q. Failing to comply with federal medical device reporting requirement to report a serious injury and/or death, as required by 21 CFR § 803 and Section 519 of the federal Act;

r. Falsely advertising that prescription colon irrigation systems as approved by the FDA can be self-administered when FDA has not approved these devices for such uses; and

s. Manufacturing prescription colon irrigation systems in Texas and failing to disclose to each purchaser through labeling or a label that the device is a prescription device.

t. Causing confusion as to the approval of a good by selling prescription colon irrigation systems without the authorization or order of a practitioner licensed in Texas;

u. Failing to disclose that prescription colon irrigation systems are only to be sold under the order or authorization of a practitioner licensed to use and order the use of such device;

v. Failing to disclose in any advertising, representations, training or publications that prescription colon irrigation systems are only to be used under the supervision of a practitioner licensed to use and order the use of such device;

w. Failing to disclose in any advertising, representations, training, or publications that colon cleansing using prescription colon irrigation systems can only be performed upon the order of a licensed practitioner;

x. Falsely representing to a consumer that colon cleansing using prescription colon irrigation systems can legally be performed without the supervision or order of a practitioner licensed to use or order the use of such device;

y. Falsely advertising that colon cleansing using prescription colon irrigation systems are appropriate for self-administration when they are not; and

z. Failing to disclose that Defendants' prescription colon irrigation systems are approved only for colon cleansing, when medically indicated, such as before radiologic or endoscopic examinations only.

68. .Plaintiff further prays that upon final hearing this Court order Defendants COLON

THERAPEUTICS, INC., and JIMMY JOHN GIROUARD, individually, to pay civil penalties to the State of Texas up to $25,000 per violation per day for each violation of §431.021 of the TFDCA, as provided in §431.0585(b) of the TFDCA.

69. Plaintiff further prays that upon final hearing that this court order Defendants COLON THERAPEUTICS, INC., and JIMMY JOHN GIROUARD, individually, to pay to the State of Texas and to the TEXAS COMMISSIONER OF HEALTH their reasonable expenses incurred in obtaining injunctive relief under §431.047 of the TFDCA, including investigative costs, court costs, reasonable attorneys' fees pursuant to § 431.047(d) of the TFDCA.

70. Plaintiff further prays that upon final hearing this Court order Defendants COLON THERAPEUTICS, INC., and JIMMY JOHN GIROUARD, individually, to restore all money or other property taken from identifiable persons by Defendants; unlawful acts or practices, or, in the alternative, award judgment for damages to compensate identifiable persons for such losses as provided in §17.47(d) of the DTPA.

71. Plaintiff further prays, that upon final hearing, this Court order Defendants COLON THERAPEUTICS, INC., and JIMMY JOHN GIROUARD, individually, to pay civil penalties of not more than $20,000.00 per violation, as provided in §17.47(c)(1) of the DTPA.

72. Plaintiff further prays that upon final hearing this Court order Defendants COLON THERAPEUTICS, INC., and JIMMY JOHN GIROUARD, individually, to pay an additional amount in civil penalties, not to exceed a total of $250,000.00, to the State of Texas, for any act or practice that was calculated to acquire or deprive money or other property from a consumer who was 65 years of age or older when the act or practice occurred as provided in §17.47(c)(2) of the DTPA.

73. Plaintiff further prays that upon final hearing that this Court order Defendants COLON THERAPEUTICS, INC., and JIMMY JOHN GIROUARD, individually, to pay to the

STATE OF TEXAS attorney fees and to pay the costs of court pursuant to the TEX. GOVT. CODE §402.006(c).

74. Plaintiff further prays that the court set this matter for trial and upon final hearing issue a permanent injunction against Defendants COLON THERAPEUTICS, INC., and JIMMY JOHN GIROUARD, individually.

75. Plaintiff further prays that upon final hearing that this Court grant all other relief to which the STATE OF TEXAS may be justly entitled.

Plaintiff State of Texas

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